UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

No. 07 Civ. 5898 (RJS)

MERCK EPROVA AG,

Plaintiff,

VERSUS

GNOSIS S.P.A. AND GNOSIS BIORESEARCH S.A.,

Defendants.

OPINION AFTER BENCH TRIAL
September 30, 2012

RICHARD J. SULLIVAN, District Judge:

Plaintiff Merck & Cie ("Merck"), formerly known as Merck Eprova AG, a producer of pharmaceutical and dietary ingredients, brings this action against Defendants Gnosis S.p.A. and Gnosis Bioresearch S.A. (collectively, "Gnosis"), manufacturers and sellers of raw ingredients to nutritional companies, for misleading advertising in connection with Gnosis's manufacture and sale of a folate nutritional ingredient. Specifically, Merck alleges that Gnosis falsely marketed its folate product using the chemical name, abbreviation, chemical formula, and Chemical Abstracts Services registry number ("CAS number") reserved for Merck's purer folate ingredients. Merck also contends that Gnosis described its ingredient in brochures, websites, and e-mails to clients using statements that only apply to the pure product manufactured by Merck. Merck seeks to hold Gnosis liable for false advertising, contributory false advertising, and deceptive trade practices under federal and New York law.

Having presided over a bench trial in this action, the Court issues the following findings of fact and conclusions of law, pursuant to Rule 52(a) of the Federal Rules of Civil Procedure. For the reasons set forth below, the Court finds that: (1) Gnosis engaged in false advertising and contributory false advertising in violation of the Lanham Act; and (2) Merck failed to meet its burden to prove that Gnosis engaged in a deceptive practice or false advertising in violation of New York state law. Accordingly, the Court hereby enters judgment for Merck and awards Merck damages in the amount of $526,994.13

plus interest, as well injunctive relief and attorneys' fees.[1]

I. PROCEDURAL HISTORY

Merck filed this action on June 21, 2007. The case was originally assigned to the Honorable Kenneth M. Karas, but was reassigned to my docket on September 4, 2007. On October 22, 2007, Merck filed an Amended Complaint, asserting six causes of action: (1) false advertising under Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); (2) contributory false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); (3) "use of false descriptions and false representations" in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(a); (4) unfair competition under New York common law; (5) deceptive trade practices pursuant to Section 349(h) of the New York General Business Law; and (6) false advertising under Section 350(e)(3) of the New York General Business Law.

After denying Gnosis's motion to dismiss the Amended Complaint for lack of personal jurisdiction, *Merck Eprova AG v. Gnosis S.p.A.*, No. 07 Civ. 5898 (RJS), 2008 WL 5336587, at *1 (S.D.N.Y. Dec. 12, 2008), the Court directed the parties to proceed with discovery. What ensued has already been the subject of a lengthy opinion concerning Gnosis's outrageous conduct in the course of discovery. *See Merck Eprova AG v. Gnosis S.P.A*, No. 07 Civ. 5898 (RJS), 2010 WL 1631519, at *1 (S.D.N.Y. Apr. 20, 2010). The Court will not repeat its findings here, other than to note that Gnosis was fined $25,000 and ordered to pay $89,921 in attorneys' fees. *Id.*

In August 2010, both Merck and Gnosis filed motions for summary judgment. (Doc. Nos. 88, 96.) The Court heard oral argument on both parties' motions, and, in a Memorandum and Order dated March 17, 2011, the Court denied Merck's motion for summary judgment in its entirety. (Doc. No. 146.) The Court granted Gnosis's motion in part, dismissing Merck's third and fourth claims, but otherwise denied the motion. *See Merck Eprova AG v. Gnosis S.P.A.*, No. 07 Civ. 5898 (RJS), 2011 WL 1142929, at *1 (S.D.N.Y. Mar. 17, 2011).

The case proceeded to trial on June 20, 2011. The trial was conducted without objection in accordance with the Court's Individual Rules for the conduct of non-jury proceedings. The parties submitted affidavits containing the direct testimony of their respective witnesses, as well as copies of all exhibits and deposition testimony that they intended to offer as evidence at trial. The parties were then invited to call those witnesses whom they wished to cross-examine at trial. In all, nine witnesses submitted affidavits, and ten witnesses testified before the Court at trial. The Court ruled on objections made with regard to statements in various witness affidavits and various exhibits. Closing arguments took place on June 30, 2011.

Each party submitted a post-trial memorandum ("Post-Trial Mem.") on August 1, 2011. On the same date, Merck filed a motion to redact portions of the trial transcript (Doc. No. 214) and renewed its motion for an

[1] On August 1, 2011, Merck filed a motion requesting the Court to find that discovery violations by Gnosis warrant an adverse inference that the allegedly missing documents would further support a finding of liability and willfulness on the part of Gnosis. The Court has already found that Gnosis is liable for violations of the Lanham Act and that these violations were willful. *See infra* Part III. Thus, even if the Court were to find that an adverse inference was warranted, it would not alter the Court's determination of the appropriate remedy. Accordingly, Merck's motion is denied as moot. (*See* Doc. No. 231.)

adverse inference (Doc. No. 216), requesting that the Court infer that documents missing as a result of Gnosis's discovery violations support a finding of liability and willfulness on the part of Gnosis. On August 2, 2011, Gnosis filed a motion to redact portions of the trial transcript and certain pre-trial submissions. (Doc. No. 223.) On March 30, 2012, the Court denied Merck's renewed motion for an adverse inference as moot (Doc. No. 231), and granted both motions to redact the transcript (Doc. No. 232).

II. FINDINGS OF FACT[2]

At the heart of this case is Gnosis's folate product, which is a mixture of the "active" S-isomer and the "inactive" R-isomer.[3] Although Gnosis's product is admittedly a mixture of these two isomers (PTO Facts ¶ 8), Gnosis used terms and the chemical formula for the pure S-isomer product in describing its product (*see infra* Parts II.C-D). Merck claims that this violates the Lanham Act and state law. Gnosis acknowledges that its product is a mixture. Nevertheless, Gnosis argues that its use of the terms describing its product is accurate based on scientific naming conventions. In addition, while acknowledging that it used the incorrect chemical formula and CAS registry number on some documents, Gnosis contends that this use was not part of an advertising campaign. Similarly, it contends that the allegedly false descriptions of its product in advertising brochures, websites, and emails to clients were also not part of an organized advertising campaign. Gnosis seeks attorneys' fees against Merck, contending that Merck filed this suit with anti-competitive motives.

A. The Parties

Plaintiff Merck is a Swiss corporation with its principal place of business in Schaffhausen, Switzerland. (PTO Facts ¶ 1.) Defendant Gnosis S.p.A. is an Italian corporation with its principal place of business in Desio, Italy, and Defendant Gnosis BioResearch S.A. is a Swiss association with its principal place of business in San Antonino, Switzerland. (*Id.* ¶ 2.) Gnosis sells its products in the United States, advertising them through product literature circulated at trade shows, information presented on the internet, and promotional materials distributed in person and via email to current and potential customers. (*Id.* ¶ 5.) The companies are competitors, as both Merck and Gnosis produce raw dietary ingredients used in the production of nutritional supplements. (*Id.* ¶¶ 3-4; Tr. 884:17-19.)

B. Stereochemistry[4]

Stereochemistry is a branch of chemistry concerned with the structure and properties of molecules. (PTO Facts ¶ 14.) Stereoisomers are molecules with the same composition of atoms and bond connectivity of atoms, but with different arrangements of those atoms in space. (Affidavit of Daniel W. Armstrong, Ph.D. dated May 17, 2011 ("Armstrong Aff."), ¶ 21.) These differences in spatial orientation result in different stereoisomers

[2] To the extent that any finding of fact reflects a legal conclusion, it shall to that extent be deemed a conclusion of law, and vice versa. As indicated, many of these factual findings are taken directly from the parties' experts' affidavits and the Joint Pretrial Order ("PTO Facts").

[3] In August 2009, Gnosis started to sell a nearly pure 6S Isomer Product. (PTO Facts ¶ 12.) That product is not at issue in this litigation. *See Merck Eprova AG v. Gnosis S.p.A.*, No. 07 Civ. 5898 (RJS), slip op. at 1 (S.D.N.Y. June 15, 2011).

[4] These facts are largely undisputed; however, the Court believes that it would be impossible to understand the contested issues in this case without a brief explanation of stereochemical terms and naming conventions.

having different physical, chemical, and biological properties. (*Id.* ¶ 22.)

Stereoisomers that are not mirror images of each other are called diastereoisomers. (*Id.* ¶ 35; *see* Affidavit of Dr. Jesse F. Gregory dated May 18, 2011 ("Gregory Aff."), ¶ 30.) Although they have the same molecular formula, virtually all of the physical, chemical, and biological properties of diastereoisomers are different. (Armstrong Aff. ¶ 37.) Accordingly, diastereoisomers of the same molecule can have vastly different effects in the human body. (*Id.*; Gregory Aff. ¶¶ 3-5.)

As explained in great detail at trial, at least three different conventions exist for the naming of stereoisomers. Under the Cahn-Ingold-Prelog priority rules, an isomer is identified as either "R" or "S" depending on the isomer's relation to the carbon atom. (PTO Facts ¶ 20.) The Fischer-Rosanoff convention labels the isomers either "D" or "L" based on the isomer's relation to the glyceraldehyde molecule. (*Id.* ¶ 21.) Another naming convention, based on optical activity, calls the isomers either "(+)" or "(-)," depending on the direction in which the isomer rotates the plane of polarized light. (*Id.* ¶ 22.) These three conventions have no direct relation to each other. (*Id.* ¶ 17; Armstrong Aff. ¶ 24.) The R/S designations are most commonly employed, with the International Union of Pure and Applied Chemistry recommending their use ("IUPAC"). (*Id.* ¶ 26.) Nevertheless, when a mixture of different isomers, rather than a pure isomer, is referenced, this may be appropriately indicated by using the symbols "D,L," "R,S," or "(±)" depending on the convention used, as a prefix before the chemical name. (Armstrong Aff. ¶ 30). Additionally, use of the chemical name with no symbol may also indicate a mixture of different isomers. (*Id.*)

Finally, optical purity refers to the degree of purity of a particular compound, relative to the presence of related compounds in the sample. (*Id.* ¶ 39.) For example, a sample containing 90% of stereoisomer A and 10% of stereoisomer B is said to be 90% optically pure. (*Id.* ¶ 40.)

C. Folates

The compound at issue in this case is a type of folate. Folate is the B vitamin that helps the body make new healthy cells. (Gregory Aff. ¶ 17.) Although all living beings require folates, they are particularly useful to promote prenatal health for expectant mothers and their fetuses and to lessen the risks of some cancers and cardiovascular diseases. (*Id.* ¶¶ 19-20.) Folic acid – which does not naturally occur in large quantities – is the primary folate form used in dietary supplements and food fortification, as it is relatively easy and inexpensive to manufacture synthetically. (*Id.* ¶ 23.) By contrast, tetrahydrofolates, which are the predominant naturally occurring forms of folates and are more easily absorbed by the human body, are much harder to manufacture. (*Id.* ¶¶ 24, 27; Affidavit of Roger Weibel dated May 20, 2010 ("Weibel Aff."), at ¶¶ 30, 33.) Each of the tetrahydrofolate forms exists in nature in the "L" stereochemical form but can also be synthetically manufactured. However, the manufacturing process yields a stereochemical mixture – that is, a mixture with two isomers: (1) the "S," "L," or "(+)" isomer, and (2) the "R," "D," or "(-)" isomer. (Gregory Aff. ¶ 24.) For convenience, the Court will refer to any product composed of the former isomer as a "6S Isomer Product" and will refer to any product composed of a mixture of the two diastereoisomers as a "6R,S Mixture Product." (PTO Facts ¶ 7.)

The substance at issue in this case is a tetrahydrofolate with two isomers, commonly called the calcium salt of 5-methyltetrahydrofolate, but also known as "5-methyltetrahydrofolic acid" or "5-MTHF."[5] (Armstrong Aff. ¶¶ 46, 54; Gregory Aff. ¶¶ 43.) While the "S" isomer exists naturally in foods and the human body, the "R" isomer is not naturally occurring and exists only in synthetically produced compounds. (Gregory Aff. ¶¶ 44.) Additionally, only the "S" isomer is active in the body, whereas the "R" isomer is inactive in the body and is arguably unhealthy. (Tr. 481:14-17; Weibel Aff. ¶¶ 51-53; Gregory Aff. ¶¶ 5, 27, 35.)

Merck's product, which is distributed under the tradename Metafolin, is a 6S Isomer Product (Weibel Aff. ¶¶ 10-11, 32), while Gnosis's product, Extrafolate, is a 6R,S Mixture Product (Revised Affidavit of Renzo Berna, dated June 6, 2011 ("Berna Rev. Aff."), ¶¶ 19, 48). Merck refers to Metafolin as L-5-methyltetrahydrofolic acid, calcium salt (the "common name") and L-5-MTHF (the "abbreviation"). (*See* Weibel Aff. ¶ 2.) Gnosis formerly used the same common name and abbreviation in connection with Extrafolate, its 6R,S Mixture Product. (*See, e.g.*, PTO Facts ¶ 8.) For a time, Gnosis used the common name and abbreviation (or their equivalents) on its product specification sheets (*see, e.g.*, PTX 10 at 108; PTX 11 at 67; PTX 25 at 4914; PTX 26 at GNO04918), product data sheets (*see, e.g.*, PTX 9 at 4159-60), material safety data sheets (*see, e.g.*, PTX 9 at 4161-62), certificates of analysis (*see, e.g.*, PTX 4 at 4284), emails to its agents and customers (*see, e.g.*, PTX 4 at 4283; PTX 12 at 186; PTX 80 at 43), purchase orders (*see, e.g.*, PTX 5 at 113; PTX 6 at 108), and other marketing materials (*see, e.g.*, PTX 15 at 3872).[6] Gnosis stopped using both the common name and abbreviation in connection with Extrafolate in March 2009, two years after the commencement of this action. (Berna Rev. Aff. ¶ 43.)

The parties disagree about the significance, under the naming conventions, of the L prefix in the common name and abbreviation. Merck's experts contend that a mixture product, like that of Gnosis, should be referred to as D,L-5-MTHF or 5-MTHF. (*See* Gregory Aff. ¶¶ 2, 32, 42.) By contrast, Gnosis argues that, under certain naming conventions, the common name and abbreviation – L-5-methyltetrahydrofolic acid, calcium salt and L-5-MTHF – could properly be used to describe its product. (*See* Affidavit of Prof. Jay S. Siegel dated May 20, 2011 ("Siegel Aff."), ¶ 6; Berna Rev. Aff. ¶ 35.)

D. The Products

Merck began selling Metafolin, its pure 6S Isomer Product, in 2002. (Weibel Aff. ¶¶ 10, 11, 32.) Merck sells Metafolin as a bulk substance for use by its customers in finished products, such as medical foods, prenatal vitamins, dietary supplements, and nutritional supplements. (*Id.* ¶ 10.) Metafolin is a result of Merck's more than forty years researching in the field of reduced folates. (*Id.* ¶ 7.) During the last ten years, Merck has

[5] The full chemical name of the "pure" 6S isomer is N-[4-[[(2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-(**6S**)-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid, calcium salt. (Armstrong Aff. ¶ 50 (emphasis in original).) The full chemical name of the 6R isomer is N-4-[[(2-amino-1,4,5,6,7,8-5-methyl-hexahydro-4-oxo-(**6R**)-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid, calcium salt. (*Id.* ¶ 51 (emphasis in original).) The chemical name of a diastereoisomeric mixture of these two isomers is N-[4-[[(2-amino-1,4,5,6,7,8-hexahydro-5-methyl-4-oxo-(**6R,S**)-pteridinyl)methyl]amino]benzoyl]-L-glutamic acid, calcium salt. (*Id.* ¶ 52 (emphasis in original).)

[6] Exhibits marked DTX were submitted by the defendant, Gnosis; PTX refers to exhibits submitted by the plaintiff, Merck.

invested more than $30 million in the field (*id.* ¶ 7), and, due to the cost and difficultly of synthesizing a pure S isomer, has spent more than $60 million on the development, testing, and manufacture of a 6S Isomer Product alone. (Gregory Aff. ¶ 59; Weibel Aff. ¶¶ 8-9, 30, 58.) As a result of this research, Merck became the first company to produce a substantially stable and pure 6S Isomer Product. (Weibel Aff. ¶ 12.) Since that time, Metafolin has become one of Merck's most important products. (*Id.* ¶ 15.) Merck and its licensees have spent over $100 million on marketing and promoting the product, and Merck's customers often tout as a selling point the fact that their products contain the substantially pure S isomer. (*Id.* ¶¶ 13, 16.)

Gnosis began selling Extrafolate in 2006. (Berna Rev. Aff. ¶ 20.) Because it is far less costly to produce the mixture product, Gnosis's 6R,S Mixture Product sold for approximately one-third the price of Metafolin. (PTX 72; PTX 81; Tr. 715:23-716:16 (noting that the 2005 price per kilo of Metafolin was $14,310.30 and the 2007 price per kilo of the Gnosis material was $4,500).) Gnosis markets its product by, *inter alia*, attending trade shows, distributing brochures, making PowerPoint presentations, maintaining a website, and making in-person visits to potential clients. (PTO Facts ¶ 11; Tr. 884:6-16.)

1. Chemical Name on Product Specification Sheets

In March 2006, as part of its marketing efforts, Gnosis's CEO, Renzo Berna, and two other employees attended a trade show in Anaheim, California to market both its 6R,S Mixture Product and a pure 6S Isomer Product. (Berna Rev. Aff. ¶ 39.) Approximately 120 to 150 visitors approached the Gnosis booth at the show. (*Id.* ¶ 27.) At the trade show, Gnosis employees presented potential customers with product specification sheets for its 6R,S Mixture Product. (*Id.* ¶ 39.) Product specification sheets are the documents used most frequently by Gnosis sales personnel in communicating to customers the exact contents of the product being sold, and the sheets are frequently requested by potential customers. (*Id.* ¶ 51.)

Though Gnosis recognizes that the chemical names for the 6R,S Mixture Product and the 6S Isomer Product are different (*id.* ¶ 41; Tr. 941:2-3), the product specification sheets for the 6R,S Mixture Product given out at the trade show contained inaccurate information. Specifically, the product specification sheet erroneously listed the chemical name for the pure 6S Isomer Product instead of that for the 6R,S Mixture Product. (Berna Rev. Aff. ¶ 51; *see* PTX 10.[7]) This product specification sheet was also sent to potential customers, both by Gnosis and by Gnosis's distributor. (*See* PTX 11; PTX 161). Although Berna testified that Gnosis corrected the product specification sheet by June 2006 (Berna Rev. Aff. ¶ 52), the incorrect sheet at the very least remained in customers' files after that date (*see* PTX 80; Tr. 719:14-724:11).

2. Common Name and Abbreviation on Brochures

Gnosis also uses brochures to advertise its 6R,S Mixture Product. (Berna Rev. Aff. ¶¶ 50, 54; Tr. 920:15-16.) It does so by

[7] Although PTX 10 is dated May 17, 2006, after the trade show, it is identified as the first edition of the product specification sheet, and Berna testified that the first edition of the product specification sheet was in use through June 22, 2006. (Berna Rev. Aff. ¶ 52.) On cross-examination, after initially making the dubious claim that PTX 10 was a product specification sheet for Gnosis's 6S Isomer Product (Tr. 956:6), Berna eventually admitted that this was the product specification sheet for the 6R,S Mixture Product (*id.* at 961:11-16).

distributing and referring to the brochures at sales presentations. (Berna Rev. Aff. ¶ 54.) In the fall of 2006, Gnosis handed out a brochure at a trade show in Las Vegas. (Tr. 919:11-12, 920:11-14; *see* PTX 15 (the brochure).) The brochure referred to Gnosis's 6R,S Mixture Product as L-5-methyltetrahydrofolate calcium salt and L-5-MTHF – the same names used by Merck for its substantially pure 6S Isomer Product. (PTX 15 at 3872-73; Tr. 918:17-25.) The brochure also listed, as features of Gnosis's product, characteristics attributed to the pure 6S Isomer Product, including, *inter alia*, that (1) it is the naturally predominant folate form, (2) it is the nutritionally active form, and (3) it is the essential form in which natural folates occur and are stored in the human bloodstream. (PTX 15.)

3. Product Data Sheets, Certificates of Analysis, and Material Safety Data Sheets

When it delivers products to its customers – manufacturers of nutritional supplements and vitamins – Gnosis attaches various technical documents, including product data sheets, certificates of analysis, and material safety data sheets. (Berna Rev. Aff. ¶ 49.) In the documents attached to its 6R,S Mixture Product, Gnosis referred to the product by the common name (L-5-methyltetrahydrofolic acid, calcium salt) or abbreviation (L-5-MTHF) of the pure 6S Isomer Product, and often described the chemical properties of the pure product, even though Gnosis's product was a mixture. (*See, e.g.*, PTX 4; PTX 10; PTX 12.) These same materials were also sent to potential, as opposed to existing, customers in order to solicit new sales. (PTX 9.)

In short, by advertising its 6R,S Mixture Product with terms commonly used to describe the 6S Isomer Product, Gnosis attempted to capitalize on Merck's premier position in the folate market – a market that Merck singlehandedly created by developing the pure isomer product. By offering a product that appeared identical to Merck's 6S Isomer Product, but that was far less costly due to its mixed chemical makeup, Gnosis captured many of Merck's former customers by underselling Merck. Consequently, Gnosis was able to take a significant portion of that market from Merck.

III. CONCLUSIONS OF LAW

As noted above, Merck alleges the following claims in this action: (1) false advertising under Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); (2) contributory false advertising under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); (3) deceptive trade practices pursuant to Section 349(h) of the New York General Business Law; and (4) false advertising under Section 350(e)(3) of the New York General Business Law.[8] To prevail on its claims, Merck has the burden of proof to present evidence in support of the allegations set forth in its Amended Complaint and to prove those allegations by a preponderance of the evidence. *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1548-49 (2d Cir. 1991). "'The burden of showing something by a preponderance of evidence . . . simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence.'" *Metro. Stevedore Co. v. Rambo*, 521 U.S. 121, 137 n.9 (1997) (quoting *Concrete Pipe & Prod. of Cal., Inc. v. Constr. Laborers Pension Trust for S. Cal.*, 508 U.S. 602, 622 (1993)). As the finder of fact, the Court is entitled to make credibility findings of the witnesses and testimony.

[8] As discussed above, the Court granted summary judgment in favor of Gnosis on Merck's claims for unfair competition under both the Lanham Act and New York law.

A. Jurisdiction

The Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338. The Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367. Venue in the Southern District of New York is proper under 28 U.S.C. § 1391.

B. Standing

"[I]n order to establish standing under the Lanham Act, a plaintiff must demonstrate (1) a reasonable interest to be protected against the alleged false advertising and (2) a reasonable basis for believing that the interest is likely to be damaged by the alleged false advertising." *Famous Horse Inc. v. 5th Ave. Photo Inc.*, 624 F.3d 106, 113 (2d Cir. 2010). It is not required that litigants be in competition, but competition is viewed "as a strong indication of why the plaintiff has a reasonable basis for believing that its interest will be damaged by the alleged false advertising." *Id.*

In the Joint Pretrial Order, Gnosis raises Merck's lack of standing under the Lanham Act as an affirmative defense. However, Merck clearly has standing to bring these claims. Merck has an established product that it advertises using the terms L-5-methyltetrahydrofolate and L-5-MTHF, and it alleges that it is being damaged by Gnosis's use of the same terms to describe its different product. While Gnosis initially argued that it and Merck are not direct competitors – a claim abandoned post-trial (*compare* Defs.' Trial Mem. at 10, *with* Defs.' Post-Trial Mem.) – direct competition is not required under the Lanham Act. In any event, the record indicates that the two companies are indeed competitors. (*See, e.g.*, Tr. 51:10-12, 1192:15-17); *see also Famous Horse*, 624 F.3d at 113 (concluding that plaintiff and defendant were competitors when the two parties sold similar goods and that plaintiff's allegation of lost sales to defendant's lower-priced counterfeit goods "constitute the competitive injury required for Lanham Act standing"). Thus, it is clear that Merck's "stake in the [folate] market gives it a 'reasonable interest to be protected against the alleged false advertising.'" *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 190 (2d. Cir. 1980) (*quoting* 1 Rudolf Callmann, Unfair Competition, Trademarks and Monopolies, § 18.2(b) at 625 (3d ed. 1967)).

Gnosis also argues that Merck lacks Article III standing to bring this action. (*See* Defs.' Trial Mem. at 9-10.) To establish Article III standing,

> a plaintiff must show [1] that he "suffered an injury-in-fact – an invasion of a legally protected interest which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical"; [2] that there was a "causal connection between the injury and the conduct complained of"; and [3] that it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision."

Carver v. City of New York, 621 F.3d 221, 225 (2d Cir. 2010) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Gnosis argues only that Merck has failed to demonstrate an injury in fact. (Defs.' Trial Mem. at 11.) The Court has no difficulty finding that Merck has suffered an injury in fact in this case. Plainly, a manufacturer such as Merck is injured when a competitor falsely advertises that its chemically distinct product is identical to the manufacturer's product.[9] Accordingly, the

[9] Apparently unconvinced by the Court's analysis of the issue in its summary judgment opinion, Gnosis also

Court concludes that Merck has standing to bring this action.

C. False Advertising Under the Lanham Act Section 43(a)(1)(B)

Merck challenges certain advertising practices in which Gnosis previously engaged, specifically: (1) the use of the full chemical name of the 6S Isomer Product in advertising the 6R,S Mixture Product; (2) the use of the common name and the abbreviation in advertising its 6R,S Mixture Product; (3) the use of the Chemical Abstracts Services registry number for the 6S Isomer Product in advertising the 6R,S Mixture Product; (4) the use of the name (6S)-5-methyltetrahydrofolic acid on documents that accompanied the 6R,S Mixture Product, and (5) various statements that appear to conflate research about the 6S Isomer Product and the 6R,S Mixture Product. (Pl. Post-Trial Mem. at 2-3.) Merck argues that these acts violated the Lanham Act. (*See id.*)

The Lanham Act expressly forbids false or misleading descriptions or representations of fact "in commercial advertising or promotion" concerning "the nature, characteristics, qualities, or geographic origin of . . . goods, services, or commercial activities." 15 U.S.C. § 1125(a)(1)(B). To establish a false advertising claim under Section 43(a) of the Lanham Act, a plaintiff must prove the following elements: (1) the defendant has made a false or misleading statement; (2) the false or misleading statement has actually deceived or has the capacity to deceive a substantial portion of the intended audience; (3) the deception is material, in that it is likely to influence purchasing decisions; (4) the defendant placed the false or misleading statement in interstate commerce; and (5) the plaintiff has been injured as a result of the misrepresentation, either by direct diversion of sales or by a lessening of goodwill associated with its products. *S.C. Johnson & Son, Inc. v. Clorox Co.*, 241 F.3d 232, 238 (2d Cir. 2001). "[T]he touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market. Proof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement." *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002).

To prove the first element of a Lanham Act claim, a plaintiff must show either: (1) that the "challenged advertisement is literally false, *i.e.*, false on its face" or (2) "that the advertisement, while not literally false, is nevertheless likely to mislead or confuse customers." *Tiffany (NJ) Inc. v. eBay, Inc.*, 600 F.3d 93, 112 (2d Cir. 2010). To be literally false, the message must be unambiguous; if the representation "is susceptible to more than one reasonable interpretation, the advertisement cannot be literally false," and the advertisement is actionable only upon a showing of actual consumer confusion. *Time Warner Cable, Inc. v. DIRECTV, Inc.*, 497 F.3d 144, 158 (2d Cir. 2007). When a plaintiff demonstrates the literal falsity of an advertisement, consumer deception is presumed. *Id.* at 153. Furthermore, injury may be presumed when the plaintiff is an obvious competitor with respect to the misrepresented product. *Reckitt Bensicker v. Motomco Ltd.*, 760 F. Supp. 2d 446, 453 (S.D.N.Y. 2011).

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renews its argument that this action is precluded by the Food, Drug, and Cosmetic Act. (Defs.' Trial Mem. at 21-22.) The Court rejects this argument, yet again, for the reasons stated in the summary judgment opinion. *See Merck II*, 2011 WL 1142929, at *6-7.

Alternatively, "plaintiffs alleging an implied falsehood are claiming that a statement, whatever its literal truth, has left an impression on the listener [or viewer] that conflicts with reality.'" *Time Warner*, 497 F.3d at 153 (quoting *Schering Corp. v. Pfizer Inc.*, 189 F.3d 218, 229 (2d Cir. 1999)). In a case where a plaintiff seeks to prove that an advertisement is implicitly false, the plaintiff must put forth extrinsic evidence of consumer deception. *Id.* However, there is a "narrow exception to this rule" – where a plaintiff demonstrates that a defendant has "intentionally set out to deceive the public, and the defendant's deliberate conduct in this regard is of an egregious nature, a presumption arises that consumers are, in fact, being deceived." *Tiffany (NJ), Inc. v. eBay, Inc.*, 04 Civ. 4607 (RJS), 2010 WL 3733894, at *3 (S.D.N.Y. Sept. 13, 2010) (quoting *Johnson & Johnson * Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.3d 294, 298 (2d Cir. 1992)); *see also Stokley Van Camp, Inc. v. Coca-Cola Co.*, 646 F. Supp. 2d 510, 527 (S.D.N.Y. 2009); *Johnson & Johnson Vision Care, Inc. v. Ciba Vision Corp.*, 348 F. Supp. 2d 165, 179 (S.D.N.Y. 2004). The burden then shifts to the defendant to show that consumers were not misled or confused. *Tiffany*, 04 Civ. 4607 (RJS), 2010 WL 3733894, at *3.

1. Use of Chemical Name and CAS Number on Product Specification Sheets

With regard to the first edition of the product specification sheets, Merck has proven that Gnosis engaged in false advertising under the Lanham Act.

First, the product specification sheets fall under the category of "commercial advertising." The sheets were not "isolated disparaging statements," *Fashion Boutique*, 314 F.3d at 57, but part of an organized campaign. Specifically, the sheets were widely distributed to attendees at the Anaheim trade show, *cf. id.* at 57 (noting that "promotion" includes displays at sales shows), and sent to potential customers by both Gnosis and Gnosis's agents. Indeed, Berna admitted that the sheets constitute advertising in his affidavit. (*See* Berna Rev. Aff. ¶¶ 50-51 (listing product specifications as a form of Gnosis's advertising).)

Second, the product specification sheets were literally false. As discussed above, though the sheets gave the chemical name and CAS number of the 6S Isomer Product, the Gnosis product in question was in fact the 6R,S Mixture Product. (*See* Berna Rev. Aff. ¶ 51; PTX 10.)

Finally, this falsehood was material. As the Court explained in its summary judgment opinion, the very nature of what a manufacturer is selling is material. *Merck Eprova AG v. Gnosis S.p.A.*, No. 07 Civ. 5898 (RJS), 2011 WL 1142929, at *4 (S.D.N.Y. Mar. 17, 2011); *see Rexall Sundown, Inc. v. Perrigo Co.*, 651 F. Supp. 2d. 9, 30 (E.D.N.Y. 2009). Berna acknowledged that the chemical name was especially important because it is the only way to distinguish between the product specification sheets for his two products, the 6R,S Mixture Product and the 6S Isomer Product. (*See* Tr. 932:7-8 ("[T]he differentiation was in the full chemical name . . . ."); *id.* at 941:2-3 ("From the product name . . . I can't tell. I have to go down to the – the full chemical name.").)

Because Merck has demonstrated the literal falsity of the product specification sheets, consumer deception – the second element of a Lanham Act – is presumed. Furthermore, by widely distributing the product specification sheets and sending them to potential customers, Gnosis placed the false statement in interstate commerce. Finally, because Merck and Gnosis are

competitors with respect to the folate products at issue, injury is presumed. Accordingly, the Court will enter judgment in favor of Merck on Merck's claims under the Lanham Act with regard to the product specification sheets.

2. Use of Common Name and Abbreviation on Brochures, Product Specification Sheets, Certificates of Analysis, and Material Safety Data Sheets

Merck has also proven that Gnosis's use of the terms L-5-methyltetrahydrofolic acid, calcium salt – the common name – and L-5-MTHF – the abbreviation – to describe its 6R,S Mixture Product in brochures, product specification sheets, material safety data sheets, and certificates of analysis is literally false and violates the Lanham Act.

First, Gnosis has used the common name and abbreviation in its advertising as part of an organized campaign. The common name and abbreviation were used on product specification sheets (*see, e.g.*, PTX 10 at 108), and brochures (*see, e.g.*, PTX 15 at 3872-73), both of which Gnosis admits were promotional activities (PTO Facts ¶¶ 5, 11). The material data safety sheets and certificates of analysis likewise use the common name and abbreviation of the pure 6S Isomer Product. (PTX 4; PTX 5; PTX 6; PTX 9; PTX 12.) Although Gnosis argues that material data safety sheets are not advertisements because they accompanied shipments to existing customers, the record indicates that Gnosis sent these documents in response to customer inquiries as well. (Defs.' Mem. 13; PTX 9.) Furthermore, the record shows that Gnosis distributed certificates of analysis widely within the industry. (Tr. 556:14-22, 912:3-7.) Thus, the material data sheets and certificates of analysis were part of Gnosis's "organized campaign" to sell the 6R,S Mixture Product to its customers.

Second, Gnosis's use of the common name and abbreviation was literally false. Merck has presented a wealth of evidence in favor of its position that the common name and abbreviation Gnosis used for Extrafolate refers only to the 6S Isomer Product. For instance, both of Merck's experts testified credibly that under the existing conventions in the scientific community, the common name and abbreviation are used only to refer to the 6S Isomer Product. (Armstrong Aff. ¶¶ 50, 61; Gregory Aff. ¶¶ 2, 40.) Moreover, Merck's usage is consistent with the terms' usage in the industry. L-5-methyltetrahydrofolate calcium salt and L-5-MTHF are identified as synonyms for the 6S Isomer Product in documents issued by both the Joint Food and Agriculture Organization of the United Nations and the World Health Organization Expert Committee on Food Additives, as well as the European Food and Safety Authority. (*See* Armstrong Aff. ¶¶ 58-59; PTX 22 at 15; PTX 23 at 1-3.) Various scientific articles cited by Merck's experts also use L-5-MTHF and/or L-5-methyltetrahydrofolic acid, calcium salt to refer to the 6S Isomer Product only, not the 6R,S Mixture Product. (*See, e.g.*, PTX 212 at 1; PTX 223 at 2; PTX 224 at 1.)[10]

Even Gnosis's own expert, Dr. Siegel, conceded that he was aware of no scientific or scholarly article in which the terms L-5-methyltetrahydrofolic acid, calcium salt or L-5-MTHF were used to refer to anything other than the pure isomer. (*See, e.g.*, Tr. 340:13-16, 342:19-22, 351:23-352:2, 572:18-21.)

[10] The fact that many of the articles were authored or allegedly "influence[d]" (a dubious allegation based largely on conjecture) by Merck is of no import, as it does not change the fact that the terms were consistently used in the manner that Merck promotes. (*See* Tr. 439:4-7, 460:20-461:19.)

The literature introduced at trial likewise demonstrated that the common name and abbreviation uniformly refer to the pure 6S Isomer Product and *not* the 6R,S Mixture Product.

Merck's argument is further supported by the fact that Gnosis referred to Extrafolate by a different nomenclature – the nomenclature that Merck argues is correctly applied to a mixture product – in its own internal documents. For example, Dr. Bianchi admitted that in the laboratory, on batch records, Gnosis referred to its product as "5-MTHF" or "6-RS 5 methyltetrahydrofolic acid of calcium," *not* as "L-5-MTHF" or "L-5-methyltetrahydrofolic acid, calcium salt." (*Id.* at 372:16-373:13; *see* PTX 181; PTX 182.) Similarly, patents filed by Drs. Valoti and Bianchi referred to the 6R,S Mixture Product as "5-MTHF," not "L-5-MTHF." (*See* Tr. 304:3-305:20; PTX 128; PTX 179.) Indeed, on cross-examination Dr. Bianchi referred to the product in question as "5-methyltetrahydrofolate." (Tr. 421:2.) In addition, Gnosis's own reports use "L" to refer to the natural isomer. (*See* PTX 206 at 4; PTX 208 at 5-6; Tr. 528:16-531:1.)

Gnosis largely relies on the testimony of Dr. Siegel to argue that its use of the common name and abbreviation when referring to the 6R,S Mixture Product was justified. In essence, Gnosis has bet the house on Dr. Siegel in the hope that his testimony on the intricacies of scientific nomenclature and naming conventions will be enough to create an ambiguity and defeat Merck's claim of literal falsity. To that end, Dr. Siegel attempted to argue that Gnosis's use of the common name and abbreviation was reasonably derived from Fischer-Rosanoff and IUPAC conventions. (*See* Tr. 653:8-18.) What followed was a largely esoteric and at times metaphysical discussion of the intricacies of scientific nomenclature and the limits of language to approximate and explain the chemical composition of stereoisomers. Although at times fascinating, the testimony was largely beside the point for the simple reason that the Lanham Act and the law generally require inquiry into whether a particular use is "susceptible to more than one *reasonable* interpretation." *Time Warner*, 497 F.3d at 158 (emphasis added).

Notwithstanding Dr. Siegel's best efforts to the contrary, Gnosis has failed to demonstrate such ambiguity here. Indeed, while the Court found Dr. Siegel to be credible, his testimony was largely irrelevant to this action, as it spoke to a theoretical use of the contested terms that bordered on the aspirational, not to how those terms are actually used. At times, Dr. Siegel seemed to delight in being a voice in the wilderness, criticizing scientists and practitioners for misusing nomenclature in their scientific articles (*see, e.g.*, Tr. 646:16-647:13), and using various terms inconsistently (*id.* at 647:21). But, even if *some* terms are misused, he ultimately did not dispute that *these* terms are consistently used in the way Merck contends that they should be. (*See id.* at 586:5-8.) In fact, neither Dr. Siegel nor Gnosis's other witnesses were able to point to a single organization or a single article that uses the common name or abbreviation in the manner Gnosis does.[11] (*See, e.g.*, *id.* at 340:13-16, 342:19-22, 351:23-352:2, 572:18-21.)

In sum, Gnosis and only Gnosis used the common name and abbreviation for the 6S Isomer Product to refer to its 6R,S Mixture

[11] Gnosis makes much of an e-mail sent by Dr. Gregory in which he stated that "[f]rom the viewpoint of chemical nomenclature, L-5-methyltetrahydrofolic acid is an ambiguous term." (DTX 69 at 1034.) However, Dr. Gregory testified credibly that he was attempting to say that the term is not the formal nomenclature and that, if asked, he would have said the term could only refer to the 6S Isomer Product. (Tr. 838:1-10.)

Product. It follows that Gnosis's use cannot alone render the meaning of these terms ambiguous. *Cf. Schering-Plough Healthcare Prods., Inc. v. Neutrogena Corp.*, Civ. No. 09-642-SLR, 2010 WL 2788240, at *1 (D. Del. July 15, 2010) (finding literal falsity where only defendant's use of term departed from norm). Indeed, having carefully considered the testimony, affidavits, and evidence introduced at trial, the Court is firmly convinced that Dr. Siegel's theories of nomenclature – which were not consulted before Gnosis embarked on its advertising campaign using the common name and abbreviations – were seized upon by Gnosis as an after-the-fact rationalization for a scheme that was animated by purely commercial, and not scientific, motives.

In addition, the Court finds Gnosis's story about how it derived its name to be simply fanciful – and false – and discounts it entirely. In his testimony on June 21, 2011, Dr. Valoti, upon whom Gnosis allegedly relied in naming its product (*see* Berna Rev. Aff. ¶ 35), said that in making the naming decision, he relied in part on two or three articles that used the term L-5-methyltetrahydrofolate, without a (+) or (-) when referring to the mixture (Tr. 249:9-14, 250:9-14). When directed by the Court to produce the articles in question, Dr. Valoti balked:

> THE COURT: You're under oath. You were testifying under oath that you recall articles that referred to the mixture as L-5-MTHF.
>
> THE WITNESS: I do not recall the article or the review or the journal. I'd have to go and review the document and then, you know, once I've reviewed the documents, then I can show it to you, and then I can show that as I was a witness.
>
> THE COURT: When was the last time you reviewed such articles?
>
> THE WITNESS: It's quite some time ago.
>
> THE COURT: When, approximately?
>
> THE WITNESS: Probably 20 days ago.
>
> THE COURT: 20 days ago. And you can't remember the names of any articles?
>
> THE WITNESS: No. I do not recall. I don't know what to say to you.
>
> THE COURT: Well, I want you to just tell me what you remember. You recall there being more than one article that referred to the mixture substance as L-5-MTHF? Yes or no, more than one article?
>
> THE WITNESS: Two or three, I'm certain.
>
> THE COURT: Certain, two or three.
>
> THE WITNESS: Okay. Perhaps even more.
>
> THE COURT: I'd like those produced to me.

(*Id.* 249:17-250:16.) The next day, Gnosis's counsel was forced to admit that Dr. Valoti's story was flatly untrue and that none of the articles referenced by Dr. Valoti "has a reference to the mixture ingredient using those terms." (*Id.* at 275:21-22.)

Gnosis argues that a ruling in Merck's favor will "turn the leading stereochemistry treatises on their heads" and that it is

improper for courts to impose definitions and naming conventions on scientists. (Defs.' Trial Mem. at 1; *see also* Tr. 595:1-596:5) To be clear, this Court's ruling does not endeavor to dictate terms to scientists or to stop Drs. Gregory, Armstrong, Siegel, and their colleagues from continuing to debate nomenclature issues at conferences and in scientific papers, none of which could possibly be construed as advertising. This case involves only the use of the common name and abbreviation as they are used today in the advertising of folate products. In this narrow application, the use of "L-5-methyltetrahydrofolate acid, calcium salt" and "L-5-MTHF" clearly refer to the pure 6S Isomer Product and only the 6S Isomer Product. Their application to the 6R,S Mixture Product is literally false.

In short, the Court finds it obvious that Gnosis's use of the common name and abbreviation in its marketing efforts was a calculated decision to copy Merck's advertising and capture a portion of Merck's market share, knowing full well that its 6R,S Mixture Product was materially distinguishable from Merck's pure 6S Isomer Product. In this regard, the Court finds Dr. Valoti and Berna to be completely non-credible and their testimony to be wholly false, a finding that will have implications for the damages in this case.

Additionally, as discussed above, Merck has met the other elements of a Lanham Act violation – consumer deception, materiality, interstate commerce, and injury to plaintiff. *See supra* Part III.C.1. Accordingly, the Court finds in favor of Merck on Merck's claims under the Lanham Act with regard to Gnosis's use of the common name and abbreviation on brochures, product specification sheets, certificates of analysis, and material safety data sheets.

3. Description of the Pure Isomer in Brochures, Material Safety Data Sheets, and Certificates of Analysis

Merck also alleges that descriptions of a pure 6S Isomer Product in Gnosis's brochures, material safety data sheets, and certificates of analysis constitute false advertising under the Lanham Act because Gnosis failed to disclose that its product is a mixture. In its brochures, Gnosis describes a pure 6S Isomer Product as one that is the natural form of folate and the essential form in which folates are stored in the human body. (PTX 14-16.) Likewise, the material safety data sheets and certificates of analysis describe chemical properties of the pure 6S Isomer Product. (*See, e.g.*, PTX 5; PTX 9.) Such statements are literally true when applied to the pure product. However, since the statements were used in connection with Gnosis's Extrafolate, which is *not* a pure 6S Isomer Product, the Court has little difficulty concluding that the statements are impliedly false and were intended to mislead customers.

As noted above, though a claim of deceptive advertising generally requires extrinsic evidence of consumer confusion to prevail, a presumption of deceit arises where a defendant is shown to have intended to mislead consumers and acted egregiously to that end. *Tiffany*, 2010 WL 3733894, at *3 (citing *Merck*, 960 F.2d at 298). In such cases, the burden shifts to the defendant to demonstrate an absence of confusion. *Id.* Here, Gnosis deliberately referred to its 6R,S Mixture Product in terms that refer only to the pure 6S Isomer Product. Further, Gnosis did so for purely commercial motives and in flagrant disregard of prevailing scientific conventions. Accordingly, the Court finds that Gnosis "intentionally set out to deceive the public," *Merck*, 960 F.2d at 298, and that Merck is entitled to a presumption of consumer

deception with regard to the brochures, material safety data sheets, certificates of analysis, and emails that Gnosis sent to customers. As a result, Merck has satisfied the first element of a Lanham Act claim.

For the reasons stated above, *see supra* Part III.C.1, Merck has also satisfied the other elements of a false advertising claim under the Lanham Act with regard to its descriptions of the pure 6S Isomer Product in brochures, material safety data sheets, and certificates of analysis. Namely, Merck has demonstrated the materiality of Gnosis's false statements and that Gnosis put the false statements in interstate commerce. Finally, because Gnosis is a competitor of Merck with respect to the folate products, injury is presumed.

Thus, because the information contained in the documents was *literally* true, but designed to make customers believe that Gnosis's 6R,S Mixture Product was, in fact, the pure 6S Isomer Product, the Court finds in favor of Merck with regard to Merck's claims that Gnosis engaged in false advertising with its brochures, material safety data sheets, and certificates of analysis.

4. Purchase Orders

Merck also seeks damages based on Gnosis's use of the abbreviation, CAS numbers, and the term "L-5-methyltetrahydrofolic acid" in purchase orders enclosed with Gnosis's 6R,S Mixture Product. While the use of the abbreviation and CAS numbers in such documents is also false when used to describe the 6R,S Mixture Product, the Court concludes that these documents did not constitute "advertising" under the Lanham Act. *Fashion Boutique of Short Hills*, 314 F.3d at 57 ("[W]hether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act [depends on whether] the contested representations are part of an organized campaign to penetrate the relevant market."). Merck has offered no evidence to suggest that the purchase orders were used to market Gnosis's 6R,S Mixture Product, as opposed to being merely included with shipments. *See Hyosung Am., Inc. v. Sumagh Textile Co.*, 934 F. Supp. 570, 580 (S.D.N.Y. 1996) (finding that "neither advertisement nor promotion [was] involved" when false description of a product was referenced on purchase orders included with shipments and not made available to the public), *rev'd on other grounds* 137 F.3d 75 (2d Cir. 1998). For the same reason, Merck's claims related to Gnosis's references to the CAS number for the 6S Isomer Product in purchase orders also fail.

D. Contributory False Advertising

In addition to its false advertising claims, Merck also brings claims for contributory false advertising. "[L]iability for trademark infringement can extend beyond those who actually mislabel goods." *Inwood Labs., Inc. v. Ives Labs., Inc.*, 456 U.S. 844, 853 (1982). "Thus, if a manufacturer or distributor [1] intentionally induces another to infringe a trademark, or [2] continues to supply its product to one whom it knows or has reason to know is engaging in trademark infringement, the manufacturer or distributor is contributorially responsible for any harm done as a result of the deceit." *Id.* at 854; *see also Societe Des Hotels Meridien v. LaSalle Hotel Operating P'ship, L.P.*, 380 F.3d 126, 133-34 (2d Cir. 2004); *Polymer Tech. Corp. v. Mimran*, 975 F.2d 58, 64 (2d Cir. 1992).

Gnosis is liable to Merck for contributory false advertising because its false use of the common name caused its distributors to also falsely advertise. For example, AHD was Gnosis's exclusive distributor of L-methylfolate products in the United States in

2006-2007. (*See* Deposition of John Alkire dated January 11, 2010 ("Alkire Dep. Tr."), 59:25-60:4.) AHD only purchased the 6R,S Mixture Product from Gnosis. (*See* Alkire Dep. Tr. 143:22-143:3.) Nevertheless, AHD's product specification sheet from 2006 – when Gnosis was selling only the 6R,S Mixture Product – states that the product being sold was L-5-methyltetrahydrofolic acid. (*See* PTX 75 at 7.) AHD also stated in a solicitation to customers on its website that it was selling L-5-Methytetrahydrofolic Acid. (PTX 159 at 379.) Berna admitted that AHD was following its lead in naming the products, at least with regard to the certificates of analysis and labeling. (*See* Tr. 916: 17-25.) The Court agrees and concludes that AHD followed Gnosis's lead in its product specification sheets and other advertising as well.

Accordingly, the Court finds that Gnosis intentionally induced AHD and others to falsely advertise and that Merck has prevailed on its contributory false advertising claim.

E. Deceptive Trade Practices and False Advertising under New York State Law

A plaintiff bringing a claim of deceptive trade practices under Section 349 of the New York General Business Law "must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act." *Stutman v. Chem. Bank*, 95 N.Y.2d 24, 29 (N.Y. 2000). A claim of false advertising under Section 350 must meet all the same elements as a claim under Section 349, as well as proof of actual reliance. *Rodriguez v. It's Just Lunch, Int'l*, No. 07 Civ. 9227 (SHS) (KNF), 2010 WL 685009, at *10 (S.D.N.Y. Feb. 23, 2010).

Corporate competitors have standing to bring a Section 349 claim if "the gravamen of the complaint [is] consumer injury or harm to the public interest." *Azby Brokerage, Inc. v. Allstate Ins. Co.*, 681 F. Supp. 1084, 1089 n.6 (S.D.N.Y. 1988). "[P]otential danger to the public health or safety" satisfies this standard. *Gucci Am., Inc. v. Duty Free Apparel, Ltd.*, 277 F. Supp. 2d 269, 273 (S.D.N.Y. 2003). However, where the "dispute[is] between competitors [and] the core of the claim is harm to another business as opposed to consumers," courts have found that the "public harm . . . is too insubstantial to satisfy the pleading requirements of § 349." *Id.* at 273.

In this case, Merck does not have standing to pursue its claims under Section 349. Although Merck's experts posit that there may be some negative health consequences associated with the R-isomer, Merck has not definitively established that these negative health consequences are also associated with the 6R,S Mixture Product. Instead, Merck's allegations focus almost entirely on losses suffered by Merck itself, not to the eventual – and theoretical – harm suffered by the public at large. *See Vitolo v. Mentor H/S, Inc.*, 426 F. Supp. 2d 28, 34 (E.D.N.Y. 2006) (finding that plaintiff had not demonstrated "consumer-oriented conduct" when the alleged harm was suffered by plaintiff himself and his business instead of consumers or the public).

Accordingly, Merck's claims under Sections 349 and 350 of the New York General Business Law must fail.

III. DAMAGES

Merck seeks monetary relief in the amount of three times Gnosis's profits from the sale of its 6R,S Mixture Product through

the end of 2009, as well as costs. (Pl.'s Post-Trial Mem. at 19-22.)

When a plaintiff establishes a violation of the Lanham Act, the plaintiff is entitled,

> subject to the principles of equity, to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action. The court shall assess such profits and damages or cause the same to be assessed under its direction. In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed. In assessing damages the court may enter judgment, according to the circumstances of the case, for any sum above the amount found as actual damages, not exceeding three times such amount. If the court shall find that the amount of the recovery based on profits is either inadequate or excessive the court may in its discretion enter judgment for such sum as the court shall find to be just, according to the circumstances of the case.

15 U.S.C. § 1117(a).

The award of profits is justified by three rationales: (1) to deter a willful wrongdoer from doing so again; (2) to prevent the defendant's unjust enrichment; and (3) to compensate the plaintiff for harms caused by the infringement. *Pedinol Pharmacal, Inc. v. Rising Pharm. Inc.*, 570 F. Supp. 2d 498, 504 (E.D.N.Y. 2008) (citing *George Basch Co. v. Blue Coral, Inc.*, 968 F.2d 1532, 1537 (2d Cir. 1992)). To prevail under these rationales, a plaintiff must prove that a defendant acted willfully. *George Basch Co.*, 968 F.2d at 1537. However, such a showing is not alone sufficient. Courts must also consider other factors, such as "(1) the degree of certainty that the defendant benefited from the unlawful conduct; (2) [the] availability and adequacy of other remedies; (3) the role of a particular defendant in effectuating the [wrongdoing]; (4) plaintiff's laches; and (5) plaintiff's unclean hands." *Id.* at 1540. The district court "exercises its discretion as to the proper weight to be given these factors under the circumstances." *Pedinol*, 570 F. Supp. 2d at 504.

The evidence adduced at trial leaves little doubt that Merck is entitled to recover Gnosis's profits from its sales of Extrafolate. Such an award is supported by all three of the rationales identified by the Second Circuit. First, the award is necessary to prevent Gnosis from falsely advertising in the future. As an initial matter, Gnosis's conduct during its advertising campaign and this litigation reveals its disdain for the law and this Court that is nothing short of appalling. Thus, Gnosis has given this Court little reason to believe that it will comply with orders that fall short of a full accounting of profits. Moreover, though Gnosis has stopped using L-5-MTHF and L-5-methyltetrahydrofolate to describe its mixture products, it had long used these terms to gain a valuable entry into the folate market, all while enhancing its ability to manufacture a pure 6S Isomer Product. If Gnosis were allowed to keep its profits, there would be no incentive for it to comply with the requirements of the Lanham Act in the future – indeed no other pharmaceutical company would be deterred from false advertising if it were thus able to gain an enviable market position with minimal financial repercussion. Second, Gnosis was unjustly enriched when it impinged on Merck's market for pure folate ingredients by falsely representing its 6R,S Mixture Product as a pure 6S Isomer Product. Third, the

record indicates that Merck lost sales to Gnosis as a result of Gnosis's false advertising. (*See* Tr. 1040:3-1041:8.)

Further, the record is clear that Gnosis deliberately and willfully engaged in false advertising as part of a strategy designed to gain its market share in the lucrative vitamin and nutritional supplement industry through deception. As noted above, Gnosis's own expert, Dr. Siegel, could provide *no* reasonable explanation for Gnosis's use of the contested terms to advertise its 6R,S Mixture Product. Instead, the Court finds that Dr. Siegel's attempt to legitimate Gnosis's marketing was merely a post-hoc justification for a naming decision divorced from scientific conventions. In fact, Gnosis's decision to use the chemical name, common name, and abbreviation of the pure 6S isomer was the result of a deceptive and willful decision to induce customers to purchase its 6R,S Mixture Product believing that it was the pure 6S Isomer Product. The fact that Gnosis referred to Extrafolate in its internal documents by the standard nomenclature employed by Merck and others for a mixture product clearly supports this finding.

If this were not enough, Gnosis's continued use of the terms L-5-MTHF and L-5-methyltetrahydrofolic acid in its advertising for almost two years after Merck initiated this suit evinces that Gnosis gave little consideration to this suit and more than supports a finding of willfulness.[12] "Although awareness of an adverse claim would not necessarily make [false advertising] willful, especially where the defendant believed in good faith [that its advertising was truthful]," where the evidence shows that the defendant "gave short shrift to plaintiff's claim out of arrogance," a finding of willful infringement is appropriate. *Stuart*, 489 F. Supp. at 832. Such is the case here. Gnosis has been giving Merck's claim "short shrift" since its inception. Indeed, as the Court discussed in its sanctions opinion, Gnosis failed to issue a litigation hold and deliberately flouted Court orders during the course of discovery. *See Merck*, 2010 WL 1631519, at *3 & n.6. The conduct of Gnosis's principal officers at trial further demonstrated Gnosis's willful infringement. As recounted above, Dr. Valoti lied when he testified on June 21, 2011 that he reviewed two or three articles that used the term L-5-methyltetrahydrofolate to refer to the R,S mixture. (Tr. 249:17-250:16.) Similarly, Dr. Valoti gave simply unbelievable testimony when questioned on the contents of a certificate of analysis he reviewed concerning the Gnosis product. (*See* Tr. 281:10-283:24.) Likewise, Berna told numerous lies in his sworn testimony. Among these lies – some of which he later acknowledged under cross-examination – were Berna's claims that Gnosis's initial product specification sheet for Extrafolate was not modeled on the sheet Gnosis requested from Merck (it was) (Tr. 1125:17-1126:5) and that the full chemical name of Extrafolate had never been misrepresented or omitted on the product's certificate of analysis (it had been) (*id.* at 917:24-918:6; *see* Berna Rev. Aff. ¶ 44). This false testimony, coupled with the other findings of Gnosis's knowing conduct, confirms that Gnosis's false advertising was willful. *See Stuart*, 489 F. Supp. at 832 (finding that jury could have found conduct was willful due to clearly false testimony because "a callous disregard for the oath, suggest[s] the possibility of an equally callous disregard for adverse rights").

Finally, in considering the other factors pertinent to an award of profits – defendant's benefit from the unlawful conduct, the

[12] Merck filed its Complaint on June 21, 2007. (Compl. at 1.) Gnosis continued using the common name and abbreviation until March 2009. (Berna Rev. Aff. ¶ 43.)

availability of other remedies, the role of particular defendants in the wrongdoing, and plaintiff's laches and unclean hands – the Court finds that the equities tip decidedly in favor of awarding Gnosis's profits to Merck. It is clear that Gnosis benefitted from its deception both in launching its product and attracting the attention of Merck's former customers. There are no other adequate remedies that would deter Gnosis from future misconduct, offset its unjust returns, and make Merck whole. Further, Gnosis was directly involved in the false advertising, with its senior executives and hired consultants deciding how to name the product. And there is no contention that Merck waited an unreasonable amount of time to bring this action, or that it has unclean hands.

Once an award of profits is deemed appropriate, a plaintiff need only prove a defendant's sale; the defendant retains the burden of proving appropriate costs or deductions. 15 U.S.C. § 1117(a); *George Basch Co.*, 968 F.2d at 1539. Merck has provided sufficient evidence of Gnosis's sales during the relevant period to arrive at a determination of profit. Gnosis sold $30,100 of Extrafolate in 2006 (PTX 137), $64,700 in 2007 (PTX 138), $45,500 in 2008 (PTX 139), and $35,364.71[13] during the first three months of 2009 (PTX 168).[14] While Gnosis has produced some evidence of costs that would limit the amount of damages awarded to Merck (*see* PTX 240; Tr. 1100:24-1102:20), it has not met its burden in this regard. This is because the costs Gnosis provides are from 2011 and 2010, well after the profits at issue here. (*See* PTX 240 at 10273-74.) Further, Gnosis provides no breakdown of costs, it merely provides a total number. (Tr. 1102:7-15, 1103:22-1105:8.) Finally, given the Court's findings about the credibility of Gnosis's witnesses, the Court is not prepared to accept these figures without justification. Accordingly, the Court finds that Gnosis's profits during the applicable period were $175,664.71.

However, this determination of profits does not sufficiently reflect the harm caused in this case. Instead, the Court finds that "the principles of equity" dictate that an award of Gnosis's profits should be enhanced to best reflect the intangible benefits that accrued to Gnosis as a result of its false advertising, primarily Gnosis's usurpation of Merck's market share. Though the plain language of the Lanham Act permits trebling of only plaintiff's damages, the Court may enhance an award of profits without identified limit to "such sum as the court shall find to be just" if "the amount of the recovery based on profits is . . . inadequate." 15 U.S.C. § 1117(a); *see Getty Petroleum Corp. v. Bartco Petroleum Corp.*, 858 F.2d 103, 109 (2d Cir. 1988) ("Unlimited enhancement or reduction of an award based on defendant's profits is permitted in order to correct inadequacy or excessiveness."); *Deering, Milliken & Co. v. Gilbert*, 269 F.2d 191, 194 (2d Cir. 1959) ("[I]t is apparent from the face of the statute that the court in formulating its award has as much discretion as to the defendant's profits as it has over the plaintiff's damages. The only difference is that the statute places no precisely stated ceiling over the amount of the defendant's profits which may be included in the award."). Thus, if there is evidence in the record to support an enhancement of defendant's profits, *BeautyBank, Inc. v. Harvey Prince LLP*, No.

[13] This amount is based on an exchange rate of 1.38 dollars for each euro. (*See* Defs.' Post-Tr. Mem. at 24.)

[14] Though Merck seeks costs for all of 2009, in determining the amount of an award of the defendant's profits, "[t]he time period for calculating that profit is the period during which the false statements were disseminated." *Pedinol Pharmacal, Inc.*, 570 F. Supp. at 505. Merck's argument that the statements must have continued to be disseminated after March is possible but not proven by the evidence.

10 Civ. 955 (DAB) (GWG), 2011 WL 671749, at *5-6 (S.D.N.Y. Feb. 24, 2011), the Court may order such an award so long as the amount "constitute[s] compensation and not a penalty," 15 U.S.C. § 1117(a), *see Doctor's Assocs. Inc. v. Agnello*, No. 08 Civ. 5452 (WHP), 2009 WL 2878098, at *2 (S.D.N.Y. Aug. 27, 2009).

The Court finds that the award of Gnosis's profits must be increased in order to fully compensate Merck for the improved market position Gnosis enjoyed solely as a result of its false advertising. At the time Gnosis entered the market, Merck was the only manufacturer of the pure S-Isomer Product. (Weibel Aff. ¶ 12.) Gnosis's false advertising allowed it to enter the lucrative methyltetrahydrofolate market, meaning Gnosis's very existence as a competitor was predicated on its misdeeds. Consequently, Gnosis's sales in that market even after it corrected its advertising – and therefore after the window for accounting – stemmed from its initial deception. Because the profits award considers only sales made during the period in which Gnosis falsely advertised, Merck has not been adequately compensated for losses incurred after this window closed. Additionally, a profits award alone cannot fully capture Merck's loss of market share, customer loyalty, and potential customers as a result of Gnosis's actions. *Cf. Mobius Mgmt. Sys., Inc. v. Fourth Dimension Software, Inc.*, 880 F. Supp. 1005, 1025 (S.D.N.Y. 1994) (enhancing monetary award to compensate plaintiff for the "difficult to quantify" loss of customer goodwill). Because it is thus impossible to return the parties to their respective positions prior to Gnosis's false advertising campaign, an enhancement is all the more appropriate. *Cf. N.Y. Racing Ass'n, Inc. v. Stroup News Agency Corp.*, 920 F. Supp. 295, 301 (N.D.N.Y. 1996) (enhancing award of defendant's profits when the court could not "compute the value of the intangible benefits [defendant] received as a result of its deliberate, flagarant, and mulish violation of [plaintiff's] mark").

Merck has requested that this Court order an award of three times Gnosis's profit – an amount the Court deems appropriate. Though an award of three times profit is an imprecise measure of compensation, the impossibility of gauging Merck's losses along with the undeniable existence of those losses makes it a proper, if crude, measure. *See Getty Petroleum Corp.*, 858 F.2d at 110 (noting that the "enhancement provision . . . was included to enable courts to redress fully plaintiffs whose actual damages were difficult to prove"). Further, while an award under the Lanham Act must promote a compensatory and not punitive purpose, it is no small matter that Gnosis may be deterred from again engaging in such brazen behavior by being required to fully account for its actions. *See id.* at 113 ("To the extent that deterrence of willful infringement is needed, the statutorily provided remedies of [the Lanham Act] are sufficient: a district court is empowered to enhance a monetary recovery of damages or profits, or to award plaintiff a full accounting of an infringer's profits." (citations omitted)). This is particularly true because the Court finds it inappropriate to grant the majority of injunctive relief Merck seeks, *see infra* Part IV; if Gnosis were not required to financially compensate Merck, it would largely benefit from its violations. Thus, the Court awards Merck damages in the amount of $526,994.13.

Finally, Merck is awarded prejudgment interest from March 2006, when Gnosis entered the market, until the date of this Opinion at the rate set forth in 26 U.S.C. § 6621(a)(2). *Cf. TigerCandy Arts, Inc. v. Blairson Corp.*, No. 09 Civ. 6215 (GBD) (FM), 2012 WL 760168, at *1 (S.D.N.Y. Feb. 23, 2012). Interest should be calculated based

on Gnosis's annual profits, accumulating from March 2006 through March 2009, and the total amount of those profits thereafter.

IV. INJUNCTIVE RELIEF

Merck further asks this Court to permanently enjoin Gnosis from: (1) labeling its 6R,S Mixture Product or any other product that is not a pure 6S Isomer Product with the name 6S-5-methyltetrahydrofolate or any synonyms thereof, (2) labeling *any* of its products with the names L-5 methyltetrahydrofolate, L-5-MTHF, or any synonyms thereof, and (3) selling any methylfolate product for five years. (Pl.'s Post-Tr. Mem. at 24.) Merck also asks the Court to order Gnosis to engage in a campaign of corrective advertising at Merck's discretion. (*Id.*)

To obtain a permanent injunction, a plaintiff must satisfy a four factor test, demonstrating: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006). "The historic purpose of an injunction is to ensure that past wrongdoing is not repeated, not to further punish the wrongdoer. Accordingly, an injunction is unnecessary if there is no reasonable likelihood that the conduct at issue will be repeated." *Pedinol*, 570 F. Supp. 2d at 507.

To prove irreparable harm, a Lanham Act plaintiff "must show two things: ([1]) that the parties are competitors in the relevant market, and ([2]) that there is a 'logical causal connection between the alleged false advertising and its own sales position.'" *Zeneca Inc. v. Eli Lilly & Co.*, No. 99 Civ. 1452 (JGK), 1999 WL 509471, at *36 (S.D.N.Y. July 19, 1999) (quoting *Carter-Wallace*, 631 F.2d at 190-91). As noted above, the Court has found that Merck and Gnosis are competitors in the market for methyltetrahydrofolate ingredients. (*See* Tr. 51:10-12, 884:17-23.) Moreover, there is certainly a logical connection between Gnosis's false advertising and Merck's sales position – Gnosis sells a cheaper competing product that it attempts to pass off as being the same as Merck's product. Therefore, the Court finds that Merck has met its burden of demonstrating irreparable harm.

While damages have partially compensated Merck for its injuries, Gnosis has still gained its market position as a result of its false advertising. The damages award, because it is based only on sales up to March 2009, does not fully compensate Merck. Accordingly, the Court finds that equitable relief is appropriate.[15]

That said, it appears to the Court that, balancing the equities and examining the public interest, Merck is entitled to some of the relief it seeks, but not the full extent. First, the Court will permanently enjoin Gnosis from labeling its 6R,S Mixture Product with the names 6S-5-methyltetrahydrofolate, L-5 methyltetrahydrofolate, L-5-MTHF, or any synonyms

[15] Gnosis contends that no equitable relief is appropriate because it voluntarily stopped using the terms at issue. (Defs.' Post-Trial Mem. at 25.) However, as Gnosis only stopped using those terms in response to this litigation, and only then after this case had been ongoing for almost two years (*see* Berna Rev. Aff. ¶ 53), the Court has no confidence that Gnosis's wrongdoing will not be repeated absent a prohibitory injunction. Indeed, Gnosis's conduct throughout this case – during discovery, in depositions, and even at trial – suggests that injunctive relief is essential to ensure future compliance.

thereof. As discussed above, Gnosis's application of these terms to its 6R,S Mixture Product is literally false, and it is well settled that there is no public interest in false advertising. *See Reckitt Benckiser, Inc. v. Motomco Ltd.*, 760 F. Supp. 2d 446, 456-57 (S.D.N.Y. 2001). While Merck seeks a broader injunction preventing Gnosis from using the terms L-5 methyltetrahydrofolate and L-5-MTHF with regard to *any* of its products, the Court sees no reason why Gnosis should be prevented from using these terms, so long as they accurately reflect the product they advertise.

The Court also denies Merck's request to ban Gnosis from the methylfolate market for a period of five years. The Court has already enjoined Gnosis from repeating the false advertising at issue and has addressed many of the concerns associated with Gnosis's unfairly acquired market position by enhancing the award of Gnosis's profits. Accordingly, a market ban for a period of five years is not "narrowly tailored to fit the specific legal violations" and imposes an "unnecessary burden[] on lawful activity." *See Waldman Pub. Corp. v. Landoll, Inc.*, 43 F.3d 775, 785 (2d Cir. 1994) (denying injunctive relief that would have prohibited defendant from publishing "adapted classics" instead of "books with a false representation as to their source" for those reasons). Furthermore, banning non-infringing Gnosis products from the market would "disserve[]" the public interest by artificially inflating prices and decreasing consumer choice. Merck cites only one case supporting the imposition of such a drastic penalty, and the Court has no difficulty distinguishing it. *Cf. E.G.L. Gem Lab Ltd. v. Gem Quality Inst., Inc.*, 90 F. Supp. 2d 277, 310 (S.D.N.Y. 2000) *aff'd*, 4 F. App'x 81 (2d Cir. 2001) (ordering permanent ban on use of corporate *name* only, where entire corporate identity had been built on false claim of association with industry leader, and endorsing use of corrective advertising in less egregious cases). Therefore, the Court will not ban Gnosis from selling methylfolate products in the United States, provided that it complies with the Court's prior directives.

Finally, the Court will order Gnosis to engage in a campaign of corrective advertising, to explain the differences between the pure 6S Isomer Product and the 6R,S Mixture Product. Such corrective advertising shall be approved by the Court, with input from Merck. Alternatively, the parties may elect to have Merck develop its own corrective advertising campaign, for which Merck shall be compensated by Gnosis.

V. ATTORNEYS' FEES

Merck also seeks attorneys' fees. In "exceptional cases," a court may award attorneys' fees to the prevailing party. 15 U.S.C. § 1117(a). "Such fees should be awarded only on evidence of fraud or bad faith." *Twin Peaks Prods., Inc. v. Publ'ns Int'l, Ltd.*, 996 F.2d 1366, 1383 (2d Cir. 1993) (internal quotation marks omitted). "Exceptional circumstances include willful infringement." *Bambu Sales, Inc. v. Ozak Trading Inc.*, 58 F.3d 849, 854 (2d Cir. 1995) (internal quotation marks omitted).

As noted above, the Court finds that Gnosis's false advertising in this case was willful and done in bad faith. In addition, much of Gnosis's litigation strategy was conducted in bad faith, with senior officials, including Berna, frustrating the litigation process at every turn, from withholding documents in discovery and obstructing depositions (*see Merck*, 2010 WL 1631519, at *1) to testifying falsely under oath at the bench trial in this action. In light of this conduct, and Gnosis's utter lack of respect for

the judicial process, the Court finds that this case is one justifying the award of attorneys' fees.[16]

VI. CONCLUSION

For the reasons stated above, the Court finds in favor of Merck on its false advertising and contributory false advertising claims under the Lanham Act, and awards damages in the amount of $526,994.13. The Court also grants injunctive relief as follows:

> (1) Gnosis is permanently enjoined from advertising its 6R,S Mixture Product with the names 6S-5-methyltetrahydrofolate, L-5 methyl-tetrahydrofolate, L-5-MTHF, or any synonyms thereof.
>
> (2) Gnosis is ordered to engage in a campaign of corrective advertising that is either approved by the Court or developed by Merck.

IT IS HEREBY ORDERED THAT, no later than October 30, 2012 Merck shall submit a fee application to the Court, including a sworn declaration providing each attorney's background, experience, and billing rate at the time the work was expended, as well as copies of the attorneys' time sheets. Gnosis may submit papers opposing the amount of fees requested, though not the imposition of fees themselves, no later than November 15, 2012.

The Clerk of the Court is respectfully directed to enter judgment in favor of Merck and to terminate the motions located at docket entries 214, 216, and 223.

SO ORDERED.

RICHARD J. SULLIVAN
United States District Judge

Dated: September 30, 2012
New York, New York

* * *

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[16] Gnosis also seeks attorneys' fees against Merck. As Merck is the prevailing party in this litigation, such fees are obviously not appropriate and the request is denied.